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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, DORIS JONES and ALFRED JONES, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT OF PLAINTIFFS DORIS AND ALFRED JONES'S CLAIMS** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

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Plaintiffs seek to avoid summary judgment by (a) impermissibly citing evidence about Bard filters (Recovery, G2, and G2X) and complications (tilt, migration, and perforation) that are not substantially similar to the fracture of Ms. Jones' Eclipse Filter; (b) drawing unreasonable inferences from Dr. Avino's testimony and the record evidence concerning fracture of the Eclipse Filter; and (c) asking the Court to create previously unrecognized duties to warn and a new cause of action under Georgia law. For each of these reasons, and as discussed in Bard's Motion, summary judgment is appropriate.[1]

A. Plaintiffs' Failure-to-Warn (Counts II, VI) and Misrepresentation (Counts VIII, XII) Claims Fail.

1. The Record Does Not Support a Reasonable Inference that Dr. Avino Read the Eclipse Filter's IFU, So No Failure To Warn Could Have Proximately Caused Ms. Jones' Alleged Damages.

Plaintiffs argue that "the facts and inferences reasonably construed in Plaintiffs favor are that Dr. Avino was fully apprised and aware of Bard's warnings in the Eclipse IFU by virtue of reading those very warnings in Bard's other IVC filter IFUs. Dr. Avino read IVC filter IFUs for Bard devices. The G2 and G2X IFUs (immediate predecessors to the Eclipse) contained the exact same warnings as were in the Eclipse IFU." (Pls. Resp. Br. at 12.) Dr. Avino never testified, however, that he read the IFUs for the G2 and G2X Filters, nor is such a conclusion a reasonable inference from his testimony (which Plaintiffs cite in their Response):

> Q. And what is – for all – globally, to all the medical devices you use, what is the instructions for use, or IFU?

[1] Indeed, as part of their response papers, Plaintiffs filed a 52-page "Omnibus Separate Statement of Facts" (Doc. 7950). The District of Arizona Local Rule 56.1(b) does not require a moving party to reply to a "controverting statement of facts" or respond to a non-moving party's "additional facts." Accordingly, Bard is not filing such a reply or response here. As noted throughout this Reply Brief, however, these allegations do not raise a genuine issue of material fact that would preclude summary judgment. Instead, Plaintiffs' reference to these allegations appears to be largely an attempt to "pack" the summary judgment record with irrelevant allegations (e.g., allegations about filters that Plaintiff did not receive). To be clear, Bard disagrees with Plaintiffs' characterization of many of these alleged "facts," even if such disagreement does not raise a genuine issue of material fact.

A. [Describes his understanding of what an IFU is.][2]

Q. And do you read the IFU?

A. Sometimes. I mean, I have read them. I don't – certainly don't read them on every package, because they're the same from the same device, but – you know, not – not all the time, but it does come up, for example, at meetings, or you're reading about and someone's discussing an issues with an IFU. You know, if something is within the IFU or not, to help define things that might be outside of the IFU but still medically indicated.

(Ex. A, Avino Dep. Tr., 46:16 to 47:20 (emphasis added).) As is clear from Dr. Avino's testimony, he was answering questions about IFUs generally, not IVC Filter IFUs, not Bard IVC Filter IFUs, and certainly not about IFUs for the G2 or G2X Filters.

The very next question that Plaintiffs' counsel asked Dr. Avino was "Do you know if you ever read the IFU for the Eclipse IVC filter?" Dr. Avino's full answer, "Not that I recall." (*Id.* at 47:21-23.) Plaintiffs' counsel then asked, "And even if you haven't read the Eclipse IFU, you're probably generally familiar with IVC filter IFUs, if they warn of things like fractures, migration, perforation, tilt; complications like that. Right? A. Yes. Yes." (*Id.* at 48:2-7.)

The above reflects the entirety of Dr. Avino's testimony on the topic of IFUs. Thus, the Plaintiffs' claim that Dr. Avino read the G2 and G2X IFUs is not correct. Moreover, Bard submits that Dr. Avino's testimony provides no basis for the factfinder to reasonably infer that Dr. Avino read the IFUs for the G2 and G2X Filters. *See, e.g., Nelson v. Pima Comm. College*, 83 F.3d 1075, 1081-82 (9th Cir. 1996) ("The mere

[2] Dr. Avino's full answer is as follows: "A. The IFU is what's printed on all devices, in terms of what the indications are, with the approval from the FDA, is my understanding of it. It's what the approved -- basically, it's the approved indications, and it's not -- but that's different than what we consider the standard of care. A lot of things are not -- a lot of things are used out of an IFU, cautiously, and just have become standard of care. There's lots of examples of things we still use appropriately that might not be in the IFU. But, in general, we certainly consider the IFU, and -- because that's what the research was done on for certain devices, and that's what the FDA is recommending, and that's what the company – and typically, that's very strongly what the company recommends." (Ex. A, Avino Dep. Tr., at 46:19 to 47:10.)

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'scintilla' of evidence is not enough to create a 'genuine issues of material fact' in order to preclude summary judgment. Likewise, mere allegation and speculation do not create a factual dispute for purposes of summary judgment.") (citations omitted). And because Dr. Avino does not recall that he read the IFU for the Eclipse Filter, Plaintiffs' failure-to-warn claims fail as a matter of law. *Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289-90 (11th Cir. 1994) ("a plaintiff's failure to read a warning . . . precludes recovery against the product's manufacturer") (applying Georgia law and collecting cases); *Camden Oil Co., LLC v. Jackson*, 609 S.E.2d 356, 358 (Ga. App. 2004) ("where a plaintiff does not read an allegedly inadequate warning, the adequacy of the warning's contents cannot be a proximate cause of the plaintiff's injuries"); *Wilson Foods Corp. v. Turner*, 460 S.E.2d 532, 534 (Ga. App. 1995) ("[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk.").

Even if Dr. Avino read the G2 and G2X Filters' IFUs, it has no bearing on whether Plaintiffs satisfied their burden of proof regarding the Eclipse Filter's warnings.[3] Indeed, Plaintiffs' argument is that the Eclipse Filter's IFU is defective because it failed to warn Dr. Avino that the Eclipse filter "experienced complications at a significantly higher rate than competitor IVC filters and Bard's SNF." (Pls. Resp. Br., at 12.) Obviously, the G2 and G2X Filter IFUs did not and could not warn Dr. Avino that the Eclipse Filter, which was not on the market yet, allegedly experienced complications at a significantly higher rate than competitor IVC filters and Bard's SNF. For this reason, Plaintiffs' argument does not make sense. Nor have Plaintiffs cited any law to support their argument.

Accordingly, Plaintiffs cannot establish the proximate cause element of their

[3] Despite Plaintiffs' assertions that "[t]he Eclipse filter is essentially the same filter as Bard's G2X IVC filter" because the addition of electropolishing was ineffective, Plaintiffs' own expert, Dr. Ritchie, conceded that electropolishing was an improvement over previous generations, including the G2X. (Dep. Tr. Dr. Robert Ritchie, 52:8-17, Aug, 4, 2017 (testifying that electropolishing could "improve surface conditions and the centerless grind issues that had been in the previous iterations"), attached as Exhibit I.)

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failure-to-warn claims, and summary judgment is appropriate.[4]

2. Bard Had No Duty To Warn about Comparative Risks

Plaintiffs conflate the issues of duty to warn with adequacy of the warning. The existence of a duty to warn is a question of law and is informed by logic, science, and public policy. *Certainteed Corp. v. Fletcher*, 300 Ga. 327, 330, 794 S.E.2d 641, 645 (2016). Plaintiffs argue that Bard had a duty to warn physicians that the Eclipse Filter "experienced complications at a significantly higher rate than competitor IVC filters and Bard's SNF." (Pls. Resp. Br. at 12.) The cases that Plaintiffs cite, however, do not address whether such a duty exists, but rather focus on whether adequacy of the warning was a question of fact for the jury. The predicate issue, however, is whether a duty to warn exists. As a matter of logic, science, and public policy, Bard submits that it has no duty to warn about comparative rates.

First, Bard can find no Georgia law creating a duty on a manufacturer to provide comparative rates of complication for its product to other similar products on the market. Rather, as discussed on pages 8 and 9 of Bard's Motion, courts that have addressed the issue have found that pharmaceutical and medical-device manufacturers have no duty to warn physicians about the risks attendant to other products and also discuss the policy reasons for their conclusions. Plaintiffs did not address any of these cases in their Response. And none of the cases that Plaintiffs cite find that such a duty exists.[5]

[4] Plaintiffs' argument that Bard was required to send a "Dear Doctor" letter, product pamphlets, and verbally inform physicians through sales representatives is not supported by the law that they cite. *Allen v. Belinfante*, 458 S.E.2d 867 (Ga. App. 1995) (finding that a letter and an FDA alert were relevant to a physician's knowledge about risks of dental implants in a malpractice action against the dentist for fraudulent concealment and failure to warn the patient about the risks he knew about); *Fouch v. Bicknell Supply Co.*, 756 S.E.2d 682 (Ga. App. 2014) (finding that a company catalog was relevant when it contained risk information that contradicted the warnings on the actual product).

[5] *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219-20 (11th Cir. 1999) (the court did not discuss whether Ford had a legal duty to provide comparative warnings, but noting that where the rollover risk for the Bronco II was higher than other cars, "a reasonable fact finder could conclude that Ford was required to provide a more detailed warning for the vehicle"); *Cason v. C.R. Bard, Inc.*, No. 1:12-CV-1288-MHS, 2015 WL 9913809, at **3-4 (N.D. Ga. Feb. 9, 2015) (although Bard argued that it had no duty to warn about comparative rates, as noted by the court, the court never addressed Bard's argument, instead skipping ahead to whether the warning was adequate); *Cisson v. C.R. Bard, Inc.*,

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Second, Bard is unaware of any FDA regulation that would require (or even permit) it to warn doctors about comparative rates of risk between the Eclipse Filter and other IVC filters. Any comparative rate information that Plaintiffs claim Bard should have included in its warnings is almost certainly precluded by FDA regulations. In the closely related pharmaceutical context, the FDA places strict limitations on when comparative claims can be made, requiring that such comparative information be the result of "adequate and well-controlled studies." *See* 21 C.F.R. § 201.57(c)(7) (2011); 21 C.F.R. § 314.126(b) (2011); *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 2466, 2473 (2013) (state law statute requiring labeling changes preempted). Moreover, Plaintiffs' regulatory expert, Dr. Parisian, testified that, per FDA regulations, Bard would not be permitted to provide the rates the Plaintiffs purport to require in their warnings. (Dep. Tr. Dr. Suzanne Parisian, 71:5-18, Sept. 25, 2014 ("the MAUDE database, it can be used for certain things, but it's not – you wouldn't use it across industry to come up with the incidence rate. And it says it on the database; don't use it as an incidence rate, but you can come up with – you can use it for certain things, but I wouldn't use it for that"), attached as Exhibit B). As discussed further below, generating reliable comparative adverse event rates across IVC filters is impossible, and therefore the rates are not the result of "adequate and well-controlled studies." If Plaintiffs' proposed comparative warnings standard were imposed on Bard when the FDA's regulations most likely would prevent Bard from providing such comparative warnings, then the Plaintiffs' claim would be preempted by federal law. *See Mut. Pharm.*, 133 S. Ct. at 2473; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (state requirements preempted if "'different from, or in addition to' the requirements imposed by federal law"); *Bass v. Stryker Corp.*, 669 F.3d

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No. 2:11-CV-00195, 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2013), *aff'd sub nom.* 810 F.3d 913 (4th Cir. 2016) (not addressing whether Bard had a duty to warn about rate and severity of complications, instead summarily noting that the issue was whether Bard's warnings were adequate, which is a question of breach; thus, the court skipped the predicate step of whether a duty actually existed to warn about rates of complications); *In re Mentor Corp.*, 711 F. Supp. 2d 1348, 1377 (M.D. Ga. 2010) (discussing adequacy of warning only, not whether a duty existed to warn about comparative rates of complication).

501, 505-06 (5th Cir. 2012) (affirming order dismissing failure to warn claims, on the basis they were foreclosed by the *Riegel* holding).

Third, meeting Plaintiffs' demand that Bard provide comparative warnings to doctors would be impossible. The data is inherently unreliable for defining actual rates. The FDA explicitly states that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices." (MAUDE – Manufacturer and User Facility Device Experience, *at* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm (last accessed Oct. 23, 2017)); *see, e.g.*, Goldman (writing for the U.S. Food and Drug Administration), *Limitations and Strengths of Spontaneous Reports Data*, 20 Clinical Therapeutics C40 (1998) (discussing the many biases in spontaneous adverse event reports, and concluding that "Numerator and denominator limitations make incidence rates computed from spontaneously reported data problematic, if not completely baseless"), attached as Exhibit C; FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment* (Mar. 2005) (discussing the numerous biases inherent in adverse event reporting, and concluding that "Comparisons of reporting rates and their temporal trends can be valuable, particularly across similar products or across different product classes prescribed for the same indication. However, such comparisons are subject to substantial limitations and interpretation because of the inherent uncertainties in the numerator and denominator used. As a result, FDA suggests that a comparison of two or more reporting rates be viewed with extreme caution and generally considered exploratory or hypothesis-generating. Reporting rates can by no means be considered incidence rates, for either absolute or comparative purposes."), attached as Exhibit D. Even Plaintiffs' biostatistician expert, Dr. Betensky, recognizes in her analysis that she is not deriving actual rates of complication, rather calling them "Reporting Risk Ratios."

And even if reliable rates for adverse events were discernible, because they would be discernable only through adverse event reports, the rates would change many times

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each day. Adverse events for IVC filters (the numerators in the rates calculation) are reported throughout the country. Moreover, Bard reports to the FDA the events that it receives through new legal complaints, and certain events reported in medical literature. And Bard's filters and other filters (the denominators in the rates calculation) are used many times throughout the country each day. Thus, throughout the day, the numbers needed to calculate the comparative rates would change for every IVC filter. By the time that Bard compiled the comparative rate data, calculated comparative rates of risk, and informed doctors of the results, the rates would be wrong because of additional reports of adverse events and additional filters used. Bard then would need to issue revised warnings documents, which likewise would be wrong by the time they were issued to doctors. Considering the volume of filter-related complications across all devices that can potentially occur each year and that tens of thousands of IVC filters are placed each year, Plaintiffs' demand for comparative rates warnings would be impossible to meet.

For all of these reasons, the Court should decline to impose a duty on Bard to warn about comparative rates of complications, and should grant Bard summary judgment on Plaintiffs' failure-to-warn claims.

3. The Eclipse Filter's IFU Was Adequate as a Matter of Law Because It Warned of the Precise Risk Experienced by Ms. Jones and No Evidence Supports that a Different Warning Would Have Caused Dr. Avino To Use a Different Filter.

Although Plaintiffs argue throughout their Response that Bard failed to sufficiently warn about tilt, migration, perforation, fracture, and death, the only adverse events that Plaintiffs allege are fracture and embolization of a fragment to the pulmonary artery. Thus, the other events that Plaintiffs argue about in their Response are irrelevant to Bard's Motion. *See, e.g., R & R Insulation Servs., Inc. v. Royal Indem.* Co., 705 S.E.2d 223, 233 (Ga. App. 2010) ("A breach of a duty to warn, however, must also be the cause of the injury about which the plaintiff complains . . . .").

As to the fracture warning in the Eclipse IFU, the plaintiffs have not identified an alternative warning as they are required to do under Georgia law. *See Nolley v. Greenlee*

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Textron, Inc., No. CIVA 1:06-CV-228 MHS, 2007 WL 5369405, at *6 (N.D. Ga. Dec. 6, 2007) (granting summary judgment because "given the Court's exclusion of [the plaintiff's expert's] testimony, plaintiff lacks essential expert evidence as to what alternative warnings should have been given and whether such warnings would have been heeded. . . . Indeed, without [the expert's] opinion, the jurors will not be presented with alternative warnings and will have no means by which to adjudge whether the existing warnings were adequate.") As such, the jury will have no means by which to determine whether the warnings were adequate, and summary judgment is appropriate.

Moreover, Plaintiffs do not cite any factual support or expert testimony that Bard's Eclipse filter fractured at a significant enough rate to render's Bard's warnings about fracture defective. Although Plaintiffs cite a variety of Bard's documents in their Response, the documents almost exclusively concern filters other than the Eclipse, and they largely concern complications other than fracture. (Pls. Resp. Br., at 3-5.) Plaintiffs appear to cite one document comparing the fracture rate of Eclipse to the SNF, and claim that "the Eclipse, even after limited sales, fractured nearly 4 times as often as the SNF." (Pls. Resp. Br. at 5.) The document cited, however, is dated June 2011, 10 months after Ms. Jones received her Eclipse Filter, and therefore cannot serve as a basis for failing to warn Dr. Avino in August 2010 about comparative rates of fracture. (Pl. OSOF ¶ 114.) And the underlying document lists a fracture rate of 0.010% for SNF and 0.036% for Eclipse. There are no studies in the medical literature concerning the fracture rate of the Eclipse Filter. And there is no evidence in the record to suggest that the Eclipse Filter fractures at rates higher than those described in any iteration of the SIR Guidelines. (*See, e.g.*, Grassi, *Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism*, 14 J. Vascular Interventional Radiology S271, S273 (2003) (discussing reported rates of fracture for all IVC filters as up to 10%), attached as Exhibit E; ACR-SIR-SPR, *Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism* (2017), at 13 (discussing reported rates of fracture for all IVC filters

as up to 50%), attached as Exhibit F.) Indeed, the Deso article, which plaintiffs' counsel and plaintiffs' experts have relied on so heavily in this litigation, does not list a fracture rate for the Eclipse Filter. (Deso, *Evidence Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type*, 33 Seminars in Interventional Radiology 93, 97 (2016), attached as Exhibit G.) Thus, to establish that Bard's warnings about fracture in the Eclipse Filter's IFU were inadequate in August 2010, the Plaintiffs are left with no evidence.

Moreover, Plaintiffs' admissions to paragraphs 15 and 18 of Plaintiffs' Controverting Statement of Facts Regarding Plaintiffs Jones establish that the Eclipse Filter IFU warned, in the bolded **Warnings** section, about the precise complications that Ms. Jones experienced. Although adequacy of warnings is often a question of fact, in situations such as these, Georgia courts have found such warnings adequate as a matter of law. *See, e.g., Thornton v. E.I. Du Pont De Nemours & Co., Inc.*, 22 F.3d 284, 289 (11th Cir. 1994) (applying Georgia law, and finding "[t]he product carried a warning of the hazards connected with its use. Said warning was reasonably calculated to reach the average user and contained clear and simple language. . . . Summary judgment is appropriate where, as in this case, the facts support only one conclusion, that is, the warning and its communication were adequate."); *Lakey v. Mentor Corp.*, Civil Action No. 1:05–cv–929–TCB, 2007 WL 4811929, at *4 (N.D. Ga. Mar. 30, 2007) (finding that failure to warn claim was barred because plaintiff alleged that product caused infection and product insert sheet warned of the risk of infection). Such a finding is appropriate here, given the lack of record evidence that Plaintiffs use to oppose Bard's Motion.

Finally, Plaintiffs' counsel did not ask Dr. Avino during his deposition whether a different warning would have changed his decision to use the Eclipse Filter for Ms. Jones. Moreover, Dr. Avino testified that that for IVC filters generally, "an acceptable rate of fractures for an IVC filter" would be "in the 5 percent range." (Ex. A, Avino Dep. Tr., 64:8-17.) The lack of testimony and the lone document that Plaintiffs cite about the Eclipse Filter having a fracture rate of 0.036%, which was derived 10 months after Ms.

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Jones received an Eclipse Filter, provides no basis for the factfinder to reasonably infer that Dr. Avino would have changed his decision to use the Eclipse Filter, particularly in favor of the SNF Filter, which Dr. Avino testified was not an option for Ms. Jones. (*Id.* at 90:24 to 91:16); *see, e.g., Nelson v. Pima Comm. College*, 83 F.3d 1075, 1081-82 (9th Cir. 1996) ("The mere 'scintilla' of evidence is not enough to create a 'genuine issues of material fact' in order to preclude summary judgment. Likewise, mere allegation and speculation do not create a factual dispute for purposes of summary judgment.") (citations omitted).

For each of these reasons, the Court should find the Eclipse Filter's warnings about fracture adequate as a matter of law.

4. The Risk of Filter Fracture Was a Generally Known In the Medical Community by August 2010

Although Plaintiffs argue that the rate of filter fracture was not generally known in the medical community in August 2010, they cite no evidence to support their claim. (Pls. Resp. Br. 14-15.) In 2001 and 2003, the SIR Guidelines listed rates of fracture for all IVC filters as reported up to 10%. And Dr. Avino testified that his understanding was that fracture rates were "in the 5 percent range." Finally, myriad articles in the medical literature before 2010, cited by Bard's experts and Plaintiffs' experts, discuss fractures of IVC filters both generally and specifically for individual filters. For example, an article published in 1993 reported on various complication rates for IVC filters available at the time, listing a 12% fracture rate for the SNF, as well as fracture rates for six other filters. (Ferris, *Percutaneous Inferior Vena Caval Filters: Follow-up of Seven Designs in 320 Patients*, 188 Radiology 851, 853 (1993), attached as Exhibit H.) Because Plaintiffs cite no evidence to oppose Bard's Motion on this point, the Court should grant summary judgment.

5. Plaintiffs Offer No Legal Authority For Separate Products Liability Misrepresentation Claims (Counts VIII, XII)

Plaintiffs' attempt to distinguish the case law that Bard cited actually bolsters

Bard's argument that they cannot maintain both a misrepresentation claim and a products liability failure-to-warn claim: "But the *Swicegood* court found the misrepresentation claim in that case was 'masquerading' as a products-liability claim . . . ." (Pls. Resp. Br. at 16.) Here, any misrepresentation claim is really a failure to warn claim, and therefore not cognizable under Georgia law.

Even if Georgia law recognized separate products liability misrepresentation claims, Plaintiffs offer no evidence of the required elements, including scienter and justifiable reliance. *Potts v. UAP-GA AG CHEM, Inc.*, 567 S.E.2d 316, 319 (Ga. App. 2002). As a result, even if recognizable, Plaintiffs' misrepresentation claims would fail.

B. Plaintiffs' Negligence *Per Se* Claim (Count IX) Fails Because Plaintiffs Have Not Provided Any Evidence that Bard Violated a State Safety Statute and Any Alleged Violation of the FDCA Would Be Preempted By Federal Law.

Plaintiffs' negligence *per se* cause of action fails because they admittedly are using a Georgia statute as a vehicle to bring a private right of action for enforcing alleged FDCA violations. (Pls. Resp. Br., at 16 ("Count IX of Plaintiffs' Master Complaint (adopted by Doris Jones) alleges that Bard was negligent per se and based upon violation of several sections of the Food Drug and Cosmetic Act, 21 U.S.C. §§ 321, 331 and 352, and various attendant regulations, specifically 21 C.F.R. §§ 1.21, 801, 803, 807 and 820."). The FDCA, however, does not provide a private right of action for a defendant's violation of its provisions. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986). Instead, "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). Accordingly, where "the existence of these federal enactments is a critical element in [Plaintiffs'] case," and where Plaintiffs' claims "exist solely by virtue of the FDCA . . . requirements," state law claims are impliedly preempted by the FDCA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Thus, Plaintiffs' negligence *per se* cause of action is

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preempted, and summary judgment is appropriate.[6]

C. Plaintiffs Have Offered Insufficient Evidence To Bring a Punitive Damages Claim.

Plaintiffs have failed to meet their high burden to establish their punitive damages claim because (1) they offer only a scattershot of allegations involving different products and complications without showing they are substantially similar to the Eclipse Filter fracture at issue in Ms. Jones' case, and (2) have not shown that Bard acted with "conscious indifference" by doing "nothing," because Plaintiffs concede that electropolishing was intended to improve fracture resistance. Punitive damages are only assessed in extreme cases in Georgia, and require clear and convincing evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to the consequences" of the tortious act. O.C.G.A. § 51-12-5.1(b).

Plaintiffs suggest that a "conscious indifference to the consequences" requires less than some intentional act. (Pls. Resp. Br. at 23.) But, Georgia law is clear that "conscious indifference to consequences means an intentional disregard of the rights of another,

[6] Plaintiffs argue that O.C.G.A. § 51–1–6 circumvents this preemption, and provides a separate cause of action, but it does not. A large a body of case law runs counter to their argument, finding that O.C.G.A. § 51–1–6 is simply a codification of the negligence *per se* doctrine, and a separate statute providing a cause of action is still required. *See e.g.*, *Hanover Ins. Co. v. Carroll*, No. 1:13–cv–01802–SCJ, 2014 WL 5472520, at *7 (N.D. Ga. Mar. 5, 2014) ("[S]upport for a claim under § 51–1–6 must be found in a legislative enactment outside of § 51–1–6."); *Coleman v. H2S Holdings, LLC*, 230 F. Supp. 3d 1313, 1321 (N.D. Ga. 2017) ("[N]one of the three Georgia statutes that Plaintiff claims Oasis violated provides a private right of action. One is a criminal statute, and the other two 'simply set forth general principles of tort law.' They authorize 'the recovery of damages for the breach of a legal duty otherwise arising, though not expressly stated, under a statute or common law.' Since Oasis violated no such duty, those statutes have no application here.") (internal quotations omitted); *see also, Dist. 65 Ret. Tr. for Members of Bureau of Wholesale Sales Representatives v. Prudential Sec., Inc.*, 925 F. Supp. 1551, 1561 (N.D. Ga. 1996) (finding fraud and negligence claims brought under O.C.G.A. § 51–1–6 were preempted by ERISA). The lone case Plaintiffs cite in support of their position, *Amick v. BM & KM, Inc.*, 275 F. Supp. 2d 1378 (N.D. Ga. 2003), also recognizes that "[w]here the cited statute does not govern the relationship between the parties, no cause of action exists [under O.C.G.A. § 51–1–6], and recovery of damages based on violation of that particular statute is unwarranted." *Id.* at 1382. The only statute that Plaintiffs' identify is the FDCA, which does not permit a private right of action.

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knowingly or willfully. *COMCAST Corp. v. Warren*, 650 S.E.2d 307, 311 (Ga. App. 2007) (citing *Read v. Benedict*, 406 S.E.2d 488 (Ga. App. 1991)) (emphasis added). *See also, Georgia Farm Bureau Mut. Ins. Co. v. Miller*, 473 S.E.2d 189, 191 (Ga. App. 1996) ("The latter expression relates to an intentional disregard of the rights of another knowingly or willfully disregarding such rights."). Thus, even clear and convincing evidence of gross negligence will not support an award of punitive damages. *COMCAST Corp. v. Warren*, 650 S.E.2d 307, 311 (Ga. App. 2007).

1. Plaintiffs Cannot Support Their Punitive Damages Claim with Different Complications Involving Different Products Without Showing Substantial Similarity.

"In product liability actions, evidence of other incidents involving the product is admissible, and relevant to the issues of notice of a defect and punitive damages, provided there is a showing of substantial similarity. Without a showing of substantial similarity, the evidence is irrelevant as a matter of law." *Ray v. Ford Motor Co.*, 514 S.E.2d 227, 230 (Ga. App. 1999). *Ray*, which is instructive here, involved inadvertent vehicle motion of a 1989 Mustang by allowing the ignition key to be removed without the vehicle being in the "park" position. *Id*. at 229. Ford kept a database, much like FDA's MAUDE database on which Plaintiffs rely, of prior instances of inadvertent vehicle movement in cars lacking the ignition locking device. But, the prior "incidents were not confined to any particular model or year and that some of the information dated back to the 1960s. Moreover, the information was encoded into the database by employees who had no personal knowledge of the events, but who were simply instructed to input the information from the various source documents into designated codes. The codes utilized were extremely broad, and any one designation could include a wide variety of fact patterns." *Id*. at 230-31. "The database also failed to take into account various underlying factors-such as whether the parking brake was engaged, whether the car was on level ground or an incline or whether the vehicle was unoccupied-because this information was unknown or missing from the source documents." *Id*. Furthermore, "the information in the database has not been

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verified, and at least some of the information is known to be inaccurate. Ford had also determined that the database contained a number of duplicate entries."

In other words, many of the problems inherent in the MAUDE database were also present in *Ray*. (*See also*, Dkt. Nos. 7288; 8221 (discussing various reliability issues comparing rates between Bard's retrievable filters, the SNF, and using the MAUDE database, in Bard's motion and reply in support to exclude Dr. Betensky).) The Georgia Court of Appeals found no error in the trial court excluding this evidence and declining to consider it for the plaintiff's punitive damages claim. Likewise, here, Plaintiffs' evidence of other incidents cannot support their punitive damages claim because they have made no showing that the documents and testimony that they cite in their Response regarding Bard's other filters and complications other than fracture are substantially similar to the fracture that occurred with Ms. Jones' Eclipse Filter. *See also, State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003) ("A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages."). As such, the Court should disregard all such evidence when considering whether the Plaintiffs have created a question of material fact concerning their punitive damages claim.

2. Plaintiffs Have Not Shown that Bard Exhibited "Conscious Indifference" By Doing "Nothing," Because Plaintiffs Concede That Electropolishing Was Intended to Improve Fracture Resistance.

Plaintiffs cannot establish that Bard acted with a "conscious indifference" that would justify imposing punitive damages. Plaintiffs rely on *Cason*, which in turn relied exclusively on *Cisson*, for arguing that "that punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do *nothing* to make it safer or to warn consumers." (Pl. Resp. Br. at 23. (*quoting Cason*, 2015 WL 9913809, at *6 (emphasis original)).)

Despite Plaintiffs claiming that the Eclipse was just a "rebranded" G2 or G2X filter, and that they were all essentially the same device (Pl. Resp. Br. at 24), Plaintiffs

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also concede that the addition of electropolishing for the Eclipse was done to be "consistent with emerging industry standards" (Pls. Resp. Br. at 21), and intended to "improve[] fracture resistance or corrosion resistance." (*Id.* at 12.) Plaintiffs dispute whether electropolishing was effective at improving fracture or corrosion resistance. However even if it did not actually improve fracture or corrosion resistance, Bard's intended design improvement, and substantial investment in making that difficult improvement, cannot be considered "nothing" or "conscious indifference" to the issue of fracture.

Plaintiffs' other assertion is that "Bard was actively engaged in the development of its complete re-design [Denali], [a]nd Bard did not employ known safety features in the Eclipse such as caudal anchors (to reduce migration) or penetration limiters [Meridian], despite the fact that both designs were available and known to improve filter performance." (Pl. Resp. Br. at 21.) This argument is also unavailing. Plaintiffs, in essence, are alleging that Bard should be liable for punitive damages because it did not invent and bring to market its subsequent generation filters by August 2010 when Ms. Jones received her filter. Plaintiffs' assertion that these design changes "were available" is simply incorrect given the extensive design, testing, and regulatory clearance processes that were required before these design changes could be safely and legally implemented.

Regarding changing its warnings, Bard's position has always been that it is precluded, both legally and practically, from including rates of complications in its IFUs. However, in the Eclipse IFU, Bard added a bolded statement regarding the importance of routine follow-up of patients following the "**Precautions**" section:

> **NOTE: Standards and guidelines developed by the Society of Interventional Radiologists recommend that patients with filters (either permanent or retrievable) be tracked and receive "routine follow-up" subsequent to the placement of the device.**

(Mot. SSOF, Ex. C, Eclipse IFU at p. 2 (also referring physicians to various medical literature regarding patient follow-up)). In other words, Bard warned of the importance of one of the main remedies that Plaintiffs seek here, medical monitoring. Moreover, the

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IFU separately referred physicians to various practice guidelines in the literature which reported complication rates for IVC filters significantly higher than Bard's internal rates. (*Id*. at 6 (referring physicians to "Practice Guideline for the Performance of Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" reporting fracture rates between two and ten percent, and "Quality Improvement Guidelines for Percutaneous Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism" reporting the same.) Again, this cannot be considered "nothing" for purposes of "conscious indifference."

Every case cited by *Cisson* shows that for punitive damages to be available, the defendant must do truly "nothing" in the face of likely and extreme injuries to show such an "entire want of care which would raise the presumption of conscious indifference to consequences." O.C.G.A. § 51-12-5.1.

- *Weilbrenner v. Teva Pharms. USA, Inc.*, 696 F.Supp.2d 1329, 1340; 1344 (M.D.Ga.2010) (finding that the "warning [for eye complications] was directed to adults only," the FDA required separate warnings for pediatric patients, like the plaintiff, and the manufacturer knew of the condition could lead to blindness and did not warn of it);

- *Mack Trucks, Inc. v. Conkle*, 436 S.E.2d 635, 640 (Ga. 1993) (punitive damages appropriate where evidence showed truck manufacturer ignored or rejected advice multiple times from its engineering division to reinforce frames, vetoed proposals to reinforce frames on new trucks, and failed to notify purchasers of frame problems);

- *Ford Motor Co. v. Stubblefield*, 319 S.E.2d 470, 476; 481 (Ga. App. 1984) (analyzing under a different legal standard whether a verdict was excessive, but finding that a manufacturer's "conscious decisions to defer implementation of safety devices" to prevent fuel tanks catching fire in collisions, and that the manufacturer made "no effort was made to inform owners" without the safety devices of the risk, supported punitive damages);

- *Ford Motor Co. v. Sasser*, 618 S.E.2d 47, 58 (Ga. App. 2005) (manufacturer was aware of a greater risk to passengers from a seat latching system which caused the seats to collapse in collisions causing spinal cord injuries, knew of an internal "recommendation for a red indicator to alert customers to an unlatched seat, [] its own concerns that a recall may be in order, and despite

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its intent to change the design of the latching system to remedy this acknowledged safety defect," "chose to do nothing to warn consumers" such as the plaintiff) (emphasis added); and

- *Reid v. BMW of N. Amer.*, 430 F.Supp.2d 1365, 1373-74 (N.D.Ga.2007) (finding punitive damages issue was for jury where the BMW defendants knew of problems with "radiator[s] explod[ing] causing boiling radiator fluid to spray onto" consumers, and there was "no evidence that *any* warnings existed") (emphasis added).

In contrast, Georgia courts have dismissed punitive damages claims in circumstances more egregious than Plaintiffs allege against Bard:

- *Hernandez v. Crown Equip. Corp.*, 92 F. Supp. 3d 1325, 1357 (M.D. Ga. 2015) ("[E]ven assuming that most or even all of the 741 accidents were sufficiently similar to the one here to impute constructive notice to Crown, forklift manufacturers clearly have to weigh the benefits of a particular design against the possibility that other risks might be increased" and "Crown was not consciously indifferent" to the risk because it made different design changes other than those proposed by the plaintiff.);

- *Moore v. Wright Med. Tech., Inc.*, No. 1:14-CV-62, 2016 WL 1298975, at *6 (S.D. Ga. Mar. 31, 2016) (finding that the plaintiff alleged a viable failure to warn claim because "Defendant published materials in which it claimed to have never experienced modular neck fractures since 1985, even though Defendant knew those statements were false," but such evidence did not justify bringing a punitive damages claim); and

- *Stuckey v. N. Propane Gas Co.*, 874 F.2d 1563 (11th Cir. 1989) (affirming the district court's finding that "the evidence did not show [the manufacturer's] culpability rose to a level sufficient to justify an award of punitive damages under Georgia law" even though "[t]he propane industry in general has long been familiar with this phenomenon of 'odor fade'" such that in certain circumstances, leaking propane would become odorless and causing a greater risk of explosions).

For all of these reasons, Plaintiffs' punitive damages claim should fail as a matter of law.

CONCLUSION

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 25th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of October 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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